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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,521	07/20/2001	Jack V. Smith		2103

7590
JACK V. SMITH
P.O. BOX 156
Arden, NC 28704

07/02/2003

EXAMINER

SODERQUIST, ARLEN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/910,521

Applicant(s)

SMITH, JACK V.

Examiner

Arlen Soderquist

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1. In the claims examiner is treating the term bromine as it is defined page 6, lines 14-27 of the instant specification to include bromine, bromates, analogs of these compounds and other compounds containing bromine capable of producing an oxidative reaction in an aqueous solution.

2. This application discloses and claims only subject matter disclosed in prior Application No. 09/556,395, filed April 24, 2000, and names an inventor or inventors named in the prior application. Accordingly, this application may constitute a continuation or division. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

3. Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 3 attempts to broaden the coverage of claim 1 by increasing the types of samples used while claim 1 is limited to urine. For examination purposes claim 1 will be treated to cover all of the samples outlined in claim 3.

4. Claims 4-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4 and 5 contain a Markush group which should have all of the elements therein listed using "and" instead of "or" as the final linker. For example, in claim 4, the proper form of the last two compounds in the first group is "aminobenzoic acid and 4-aminoantipyrine".

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 1-3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eldan in view of Douglas and Dunn. In the abstract Eldan teaches biological monitoring of workers' exposure to bromine. The use of serum bromine (referring to any form of Br) concentration (SeBr) as a measure of exposure was examined in an occupational cohort. Associations with work site, department type, chemical handling, and occupation, as proxy measures of exposure, were studied. SeBr was associated with all of these measures. SeBr was also associated with various demographic characteristics (age, country of origin, and education) in men. In women, there was no association between SeBr and age, country of origin, or education. The use of SeBr as a measure of exposure is discussed. The conclusion is that exposure to bromine can be assessed by regular monitoring of SeBr. Eldan does not teach measuring bromine with a test strip or dipstick type of device and does not teach other types of biological fluids for measuring of bromine.

In the published application Douglas teaches a direct reading chemical test strip for aqueous solutions. A chemical test strip is described that is comprised of a support layer, a first assay area, a second assay area, and a hydrophobic zone positioned between the first assay area and the second assay area. The first and second assay areas are attached to the support layer and comprise an absorbent matrix. The first assay area includes a first test reagent absorbed in its matrix that changes color in response to a first concentration of an analyte such as free available chlorine (Cl). The second assay area includes a second test reagent absorbed in its matrix that changes color in response to a second concentration of the analyte. Interpretation of the test strip can be facilitated by printing information on the assay areas, which is more visible after the color change than before the color change. An example (example 1) describes a test strip for the detection of Cl in an aqueous sample such as pool or hot tub water by using 3,5,3',5'-tetramethylbenzidine and syringaldazine in the presence of buffers as color reagents that can detect different concentrations of Cl on the same strip. Page 4 lines 12-22 discuss the device shown in figure 1 and include that any type of chemical system capable of detecting aqueous analytes can be used including those for chlorine and bromine. Example 2 is directed toward

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bromine determinations. In the background section Douglas discusses problems with using photometric instruments (cost, calibration and maintenance) and with prior dipstick type measuring devices (color matching errors) which are overcome with the disclosed devices.

In the abstract Dunn discusses detection of bromate in blood and urine. To 2 ml. of plasma or urine, add 1 ml. of 4 N HCl. Centrifuge. Add 0.1 ml. of 0.01% aqueous solution of Evans blue. Immediate fading of the blue color indicates the presence of bromate at a level of 1 mg. % or more. Nitrite interferes but may be removed by the addition of 0.25 g. of urea. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the test strip of Douglas in the method of Eldan because of the ability to measure bromine in aqueous samples and the advantages of the detection as taught by Douglas. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the measurements on other biological fluids such as urine because as shown by Dunn there would be an expectation of the presence of bromine compounds in urine and the ability to make a colorimetric measurement of the level of bromine compounds present.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,537,823. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are of a scope that completely encompasses the patented claims.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art relates to reagents for detection of oxidative compounds.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (703) 308-3989. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

For communication by fax to the organization where this application or proceeding is assigned, (703) 305-7719 may be used for official, unofficial or draft papers. When using this number a call to alert the examiner would be appreciated. Numbers for faxing official papers are 703-872-9310 (before finals), 703-872-9311 (after-final), 703-305-7718, 703-305-5408 and 703-305-5433. The above fax numbers will generally allow the papers to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

A handwritten signature in black ink, reading "Arlen Soderquist". The signature is fluid and cursive, with the first name "Arlen" and last name "Soderquist" clearly distinguishable.

June 30, 2003